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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,651	02/11/2004	Rafail Zubok	532/2x5(F-280 Cont IV)	3384
27538	7590	06/24/2004	EXAMINER	
KAPLAN & GILMAN, L.L.P. 900 ROUTE 9 NORTH WOODBIDGE, NJ 07095			MILLER, CHERYL L	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/776,651	<b>Applicant(s)</b> ZUBOK ET AL.	
	<b>Examiner</b> Cheryl Miller	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is/are objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/11/04</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the limitation "the differing radii of curvature of the convex arcs" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "The apparatus of claim 1" to recite --the apparatus of claim 11--.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 16-18; and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Ferree et al. (US2004/0024462 A1). Referring to claim 1, Ferree discloses an apparatus for replacing a portion of an intervertebral disc [0002] comprising a first member (top member in figures) having a first vertebral contact surface (top surface) and a first articulation surface

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(bottom surface) defined by a plurality of concave arcs (one concave arc seen in fig.3b, another exist from the opposite view, also shown in fig.4a) each having a respective radius of curvature about a corresponding axis perpendicular to an anterior-posterior plane of the spinal column, and a plurality of convex arcs (one convex arc seen in fig.3a, another exists from the opposite view, and is also seen in fig.4b-4e) each having a respective radius of curvature about a corresponding axis perpendicular to a lateral plane of the spinal column, and a second member (bottom member) having a second vertebral contact surface (bottom surface) and a second articulation surface (top surface) that is defined by a plurality of convex arcs (one convex arc seen in fig.3b, another exists a view opposite of this view and is also seen in fig.4a) each having a radius of curvature about a corresponding axis substantially perpendicular to the anterior-posterior plane of the spinal column, and a plurality of concave arcs (a concave arc seen in fig.3a, another exists on an view opposite of this, and is also seen in fig.4b-4e) each having a radius of curvature about a corresponding axis perpendicular to the lateral plane of the spinal column, wherein an intervertebral disc space is defined between the first and second endplates of the first and second vertebral bones, and the radii of curvature of the first and second articulation surfaces are sized such that the first and second articulation surfaces engage one another when the first and second members are disposed in the intervertebral disc space to enable the first and second vertebral bones to articulate in at least one of flexion, extension, and lateral bending [0007, 0024].

Referring to claims 2-3, Ferree discloses at least one of the axes perpendicular to the anterior-posterior plane of the spinal column being coaxial, or the axes perpendicular to the lateral plane of the spinal column being coaxial. Ferree discloses at least one of the axes perpendicular to the anterior-posterior plane of the spinal column lie in a plane that is

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substantially perpendicular to the anterior-posterior plane, or the axes perpendicular to the lateral plane of the spinal column lie in a plane that is substantially perpendicular to the lateral plane (see figures).

Referring to claim 4, Ferree discloses at least one of the concave arcs of the first articulation surface having a radius of curvature A (top member seen in fig.3b, 4a) about a first axis substantially perpendicular to the anterior-posterior plane of the spinal column, and at least one of the convex arcs of the first articulation surface having a radius of curvature B (top member seen in fig.3a, 4b-4e) about a first axis substantially perpendicular to the lateral plane of the spinal column, and at least one of the convex arcs of the second articulation surface having a radius of curvature C (bottom member seen in fig.3b, 4a) about a second axis substantially perpendicular to the anterior-posterior plane of the spinal column, and at least one of the concave arcs of the second articulation surface having a radius of curvature D (bottom member seen in fig.3a, 4b-4e) about a second axis substantially perpendicular to the lateral plane of the spinal column.

Referring to claim 5, Ferree discloses the concave arcs of the first articulation surface having the same radius of curvature, the convex arcs of the first articulation surface having the same radius of curvature, the convex arcs of the second articulation surface having the same radius of curvature, and the concave arcs of the second articulation surface having the same radius of curvature (A center of rotation is disclosed in each plane, therefore, the radius will be the same at any cross section along the plane, [0024-0026], also, since the radius of curvature is not disclosed to be varied in one plane, is it assumed it is constant).

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Referring to claims 16-18 and 20, Ferree discloses the articulation members sized and shaped to engage one another and enable the vertebral bones to axially rotate through a range of angles, without displacing the bones away from one another until outside the range of angles, and maintaining point-to-point contact during flexion, extension, lateral bending, and/or axial rotation ([0007, 0024], rotation is disclosed to be limited, therefore, it is inherent that it occurs at a limited amount, range of angles as claimed).

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Shelokov (USPN 6,039,763). Referring to claim 1, Shelokov discloses an apparatus for replacing a portion of an intervertebral disc (col.1, lines 4-6) comprising a first member (1) having a first vertebral contact surface (2) and a first articulation surface (3) defined by a plurality of concave arcs (seen in fig.1b, 1c, one extending from point 4 to 5 in fig.1b, and another exists in a view opposite of this one) each having a respective radius of curvature about a corresponding axis perpendicular to an anterior-posterior plane of the spinal column, and a plurality of convex arcs (seen in fig.1a, 1c) each having a respective radius of curvature about a corresponding axis perpendicular to a lateral plane of the spinal column, and a second member (10) having a second vertebral contact surface (11) and a second articulation surface (12) that is defined by a plurality of convex arcs (seen in fig.2b, 2c) each having a radius of curvature about a corresponding axis substantially perpendicular to the anterior-posterior plane of the spinal column, and a plurality of concave arcs (seen in fig.2a, 2c) each having a radius of curvature about a corresponding axis perpendicular to the lateral plane of the spinal column, wherein an intervertebral disc space is defined between the first and second endplates of the first and second vertebral bones (fig.7), and the radii of

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curvature of the first and second articulation surfaces are sized such that the first and second articulation surfaces engage one another when the first and second members are disposed in the intervertebral disc space to enable the first and second vertebral bones to articulate in at least one of flexion, extension, and lateral bending (fig.3a-4b; col.4, lines 13-24).

Referring to claims 2-3, Shelokov discloses at least one of the axes perpendicular to the anterior-posterior plane of the spinal column being coaxial, or the axes perpendicular to the lateral plane of the spinal column being coaxial. Shelokov discloses at least one of the axes perpendicular to the anterior-posterior plane of the spinal column lie in a plane that is substantially perpendicular to the anterior-posterior plane, or the axes perpendicular to the lateral plane of the spinal column lie in a plane that is substantially perpendicular to the lateral plane (see figures).

Referring to claim 4, Shelokov discloses at least one of the concave arcs (fig.1b, 1c, extending from 4 to 5) of the first articulation surface (3) having a radius of curvature A about a first axis substantially perpendicular to the anterior-posterior plane of the spinal column, and at least one of the convex arcs (seen in fig.1a, 1c) of the first articulation surface (3) having a radius of curvature B about a first axis substantially perpendicular to the lateral plane of the spinal column, and at least one of the convex arcs (seen in fig.2b, 2c) of the second articulation surface (12) having a radius of curvature C about a second axis substantially perpendicular to the anterior-posterior plane of the spinal column, and at least one of the concave arcs (fig.2a, 2c) of the second articulation surface (12) having a radius of curvature D about a second axis substantially perpendicular to the lateral plane of the spinal column.

Referring to claims 5-6, 8-11, and 13-15, Shelokov discloses the concave arcs of the first articulation surface having the same or differing radii of curvature, the convex arcs of the first articulation surface having the same or differing radii of curvature, the convex arcs of the second articulation surface having the same or differing radii of curvature, and the concave arcs of the second articulation surface having the same or differing radii of curvature (shown as being the same in the figures, however disclosed as being the same or differing, col.10, lines 1-10).

Referring to claims 7 and 12, Shelokov discloses concave arcs being of different radii of curvature than the convex arcs (col.3, lines 66-67; col.5, lines 58-63; col.8, lines 39-42).

Referring to claims 16-20, Shelokov discloses the articulation members (3, 12) sized and shaped to engage one another and enable the vertebral bones to axially rotate through a range of angles, plus/minus three degrees, without displacing the bones away from one another until outside the range of angles, and maintaining point-to-point contact during flexion, extension, lateral bending, and/or axial rotation (see figures, col.4, lines 13-24; col.5, lines 46-52).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



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